IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

IN RE: AREDIA AND ZOMETA PRODUCTS LIABILITY LITIGATION	) NO. 3:06-md-1760) JUDGE CAMPBELL
This Document Relates to Case No. 3:06-0521 (Brodie)	)

MEMORANDUM

Pending before the Court is Defendant's Motion for Summary Judgment (Docket No. 2303). For the reasons stated herein, Defendant's Motion is GRANTED in part and DENIED in part.

FACTS

Plaintiff Sharon Brodie has brought this action against Novartis, alleging that its drug Zometa caused her deceased husband to develop osteonecrosis on the jaw ("ONJ"). Plaintiff alleges claims for strict liability (design defect and failure to warn), negligence, breach of express warranty, and breach of implied warranty. Defendant has moved for summary judgment on all claims.

SUMMARY JUDGMENT

Summary judgment "should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). In deciding a motion for summary judgment, the Court must review all the evidence, facts and inferences in the light most favorable to the nonmoving party. *Van Gorder v. Grand Trunk Western Railroad, Inc.*, 509 F.3d 265, 268 (6th Cir. 2007). In order to defeat a summary judgment motion, the nonmoving party must provide more than a scintilla of evidence; that is, the nonmoving party must present evidence sufficient to permit a reasonable jury to find in its favor. *Van Gorder*, 509 F.3d at 268.

Entry of summary judgment is appropriate against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's cases, and on which that party will bear the burden of proof at trial. *Id.*

CAUSATION

Under Missouri law, which must be applied in this case, a plaintiff is required to establish a causal connection between the defendant's conduct and the plaintiff's injury in both negligence and strict liability claims. *Chism v. W.R. Grace & Co.*, 158 F.3d 988, 991 (8th Cir. 1998). To establish the necessary causal connection, the plaintiff must prove both causation in fact ("but for" causation) and proximate causation. *Id.*

The cause in fact is determined by asking whether the plaintiff's injury would not have occurred but for the defendant's conduct. *Wright v. Barr*, 62 S.W.3d 509, 524 (Mo. Ct. App. 2001). A defendant's conduct is the proximate cause of the plaintiff's injury if the injury was the natural and probable consequence of the defendant's conduct. *Id.* If there is a sophisticated injury that requires surgical intervention or other highly scientific techniques for diagnosis, expert medical testimony is required to prove causation. *Id.* Evidence of causation must be based on probative facts, not on mere speculation or conjecture, but plaintiff is not require to exclude all other possible causes or to prove an absolutely positive causal connection. *Kircher v. Purina Mills, Inc.*, 775 S.W.2d 115, 117 (Mo. 1989).

Defendant first contends that Plaintiff's claims must fail because she cannot establish general causation, a required element of all her claims. Defendant bases this argument on its Motion for Summary Judgment Based upon a Failure of General Causation Proof under *Daubert.* The Court has

denied that motion and found that there are genuine issues of material fact as to whether Zometa and Aredia generally can cause ONJ.

Next, Defendant argues that Plaintiff cannot prove specific causation; that is, that Zometa proximately caused Mr. Brodie's ONJ. Defendant has moved to exclude Plaintiff's non-retained specific causation experts, and the Court has not considered the causation testimony of those witnesses. Plaintiff has offered the opinion of a retained expert, however, on specific causation, Dr. Marx. For purposes of summary judgment, the Court has denied Defendant's motion to exclude the testimony of Dr. Marx under *Daubert*. Defendant's arguments go to the credibility and weight of Dr. Marx's testimony, not its admissibility.

Plaintiff has not cited the Court to an expert report of Dr. Marx concerning Mr. Brodie. The Court has found, however, deposition testimony in which Dr. Marx states that Zometa was the sole cause of Mr. Brodie's exposed bone. Docket No. 2631, Ex. U, p.1078. In addition, the Court has found testimony from Dr. Marx which states that he ruled out the possibility that the exposed bone would have occurred in Mr. Brodie absent his Zometa therapy. *Id*., p. 1132. Finally, Dr. Marx testified that, in his opinion, Mr. Brodie's condition was not anything other than bisphosphonate-induced osteonecrosis. *Id*., p. 1139.[1]

Considering this testimony of Dr. Marx, for purposes of summary judgment, the Court finds that Plaintiff has carried her burden of demonstrating a genuine issue of material fact as to whether Zometa caused Mr. Brodie's ONJ. Defendant's Motion on the issues of causation is denied.

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[1] The Court also notes Dr. Marx's October 6, 2008 Affidavit, which states: "Mr. John Brodie developed Bisphophonate Induced Osteonecrosis of the Jaw while using of (sic) a specific bisphosphonate - Zometa." Docket No. 2394-38. This statement alone does not constitute an opinion that Zometa *caused* Mr. Brodie's ONJ, however.

FAILURE TO WARN

Defendant maintains that Plaintiff cannot show, by admissible evidence, that Novartis' warnings were inadequate, for the reasons stated in Defendant's Motion for Summary Judgment on the Adequacy of its Aredia and Zometa Warnings. The Court has found that there are genuine issues of material fact as to the adequacy of Defendant's warnings and denied that Motion.

Next, Defendant contends that Plaintiff cannot prove that the alleged inadequate warnings proximately caused Mr. Brodie's ONJ. Causation is a required element of a failure to warn products liability case in Missouri, and Missouri applies a two-pronged test. *Mothershead v. Greenbriar Country Club, Inc.*, 994 S.W.2d 80, 89 (Mo. Ct. App. 1999). The first prong of the causation test requires proof of a proximate causal link between the injury and the product allegedly lacking an adequate warning. *Id*. The second prong requires that the plaintiff show that a warning would have altered the behavior of those involved. *Id.*[2]

Missouri, like several other states, aids plaintiffs in proving the second prong of this test by presuming that a warning would have been heeded. *Arnold v. Ingersoll-Rand Co.*, 834 S.W.2d 192, 194 (Mo. 1992). The presumption assumes that a reasonable person will act appropriately if given adequate information. *Id.*[3]

In order for plaintiffs to prove that the allegedly deficient warnings proximately caused plaintiffs' injuries, even assuming the warnings were inadequate, plaintiffs must show that a proper

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[2] The causation elements are the same for both strict liability and negligent failure to warn. *Smith v. Brown & Williamson Tobacco Corp.*, 275 S.W.3d 748, 788 (Mo. Ct. App. 2008).

[3] This presumption arises only when there is sufficient evidence from which a jury could find that the plaintiff did not already know of the specific danger involved. *Menz v. New Holland North America, Inc.*, 507 F.3d 1107, 1112 (8th Cir. 2007).

warning would have changed the decision of the treating physician; *i.e.*, that but for the inadequate warning, the treating physician would not have used or prescribed the product. *Madsen v. American Home Products Corp.*, 477 F.Supp.2d 1025, 1035 (E.D. Mo. 2007).

Dr. Schultz stopped Mr. Brodie's Zometa treatments when Mr. Brodie started complaining of jaw pain. Docket No. 2306-34. He testified that Zometa was permanently suspended or discontinued and he would not have reconsidered Zometa treatment with Mr. Brodie's jaw problem. Docket No. 2306-5, p. 86. For purposes of summary judgment, Defendant has not rebutted the presumption that an adequate warning would have been read and heeded. There are genuine issues of material fact as to whether different warnings would have changed the behavior of Mr. Brodie or his treating physicians.

DESIGN DEFECT

Under Missouri law, to prevail under a theory of defective design, a plaintiff must demonstrate (1) the defendant sold the product in the course of its business, (2) the product was then in a defective condition or unreasonably dangerous when put to a reasonably anticipated use, (3) the product was used in a manner reasonably anticipated, and (4) the plaintiff was injured as a direct result of such defective condition. *Menz v. New Holland North America, Inc.*, 507 F.3d 1107, 1114 (8th Cir. 2007).

Defendant claims that it is entitled to the protections of comment k to the Restatement (Second) of Torts, § 402A, which recognizes that certain useful and desirable products are incapable of being made safe for their intended and ordinary use. *Pollard v. Ashby*, 793 S.W.2d 394,398 (Mo.

Ct. App. 1990). Comment k would impose liability on a drug manufacturer only if it failed to warn of dangerous propensities which it either knew or should have known. *Id*. at 399.[4]

Comment k itself, quoted in *Pollard*, states: "The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk." *Pollard*, 793 S.W.2d at 399 (emphasis added).

In order to receive the protection of comment k, the manufacturer must show (1) the drug's risk is unavoidable and (2) the overall benefit of the drug outweighs the risk created by it. *Wright v. American Home Products Corp.*, 2008 WL 1820902 at * 3 (W.D. Mo. April 18, 2008) (citing *Pollard)*. The second element is necessarily fact-intensive. *Id*.

Here, there are genuine issues of material fact as to whether the benefits of this product outweigh the risks. Defendant's entitlement to the protection of comment k cannot be determined on a motion for summary judgment. In any event, whether Novartis' product was defectively designed because of inadequate warnings also involves issues of fact which preclude summary judgment on this issue.

EXPRESS WARRANTY

Plaintiff has not responded to Defendant's arguments concerning her breach of express warranty claim. Plaintiff has offered no evidence of the existence of an express warranty upon

[4] Comment k, in Missouri, applies only where there is an alleged design defect (not failure to warn or manufacturing defect). *Pollard*, 793 S.W.2d at 400.

which her husband and/or his treating physicians relied with regard to his Zometa treatments. Therefore, Defendant's Motion for Summary Judgment is GRANTED on this claim, and Plaintiff's claim for breach of express warranty is DISMISSED.

IMPLIED WARRANTY

Missouri law provides for an implied warranty of merchantability in the sale of goods. Mo. Ann. Stat. § 400.2-314. To be merchantable, goods must be, among other things, adequately contained, packaged, and labeled. *Id.* In order to recover under this statute, a plaintiff must prove that a merchant sold goods which were not "merchantable" at the time of the sale, and injury to the plaintiff caused proximately and in fact by the defective nature of the goods, and notice to the seller of the injury. *Metty v. Shurfine Central Corp.*, 736 S.W.2d 527, 530 (Mo. Ct. App. 1987).

As explained above, there are genuine issues of material fact in this case as to whether Zometa was adequately labeled. Therefore, Defendant's Motion for Summary Judgment on the breach of implied warranty claim is denied.

CONCLUSION

For all these reasons, Defendant's Motion for Summary Judgment (Docket No. 2303) is GRANTED in part and DENIED in part. Plaintiff's claim for breach of express warranty is DISMISSED.

IT IS SO ORDERED.

Todd Campbell

TODD J. CAMPBELL
UNITED STATES DISTRICT JUDGE